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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,196	12/04/2001	Keith D. Allen	R-632	6896

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DELTAGEN, INC.
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/17.

Office Action Summary	Application No. 10/005,196	Applicant(s) ALLEN ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 8, 9, 23, 29-32 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 8, 9, 23, 29-32 and 35-39 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/04/2001 and 06/23/2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

Applicant's amendment filed on 03/15/2004 has been entered. Claims 1-5,7,10-22, 24-28,33 and 34 have been cancelled. Claims 6,23,30,31,32 and 37 have been amended. Claims 6,8,9,23,29-32 and 35-39 are pending and under consideration in the instant action.

Claim Objections

Claim 29 is objected to because of the following informalities: Claim 6 recites the term "claim-6" in step (a). It appears that this is a typographical error. It cannot be determined if the "-" is a strikethrough of the space between "claim" and "6" or if a number has been omitted, indicating that claim 29 is a multiple dependent claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101/112-1st paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 6,8,9,23,29-32 and 35-39 under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility is maintained for reasons of record set forth on pages 3-5 of the previous office action mailed 09/10/2003. Applicant's arguments have been fully considered and are not persuasive.

Art Unit: 1632

The claims are directed to a transgenic mouse whose genome comprises a disruption in the FPR-RS4 gene, and wherein the mouse exhibits relative to a wild-type mouse, increased anxiety, decreased coordination, impaired balance, or decreased susceptibility to seizure. The claims are further directed to cells and tissues isolated from the same mouse and methods of screening agents that may modulate the claimed phenotypes using the same mouse.

Applicant argues that there is a direct correlation between the FPR-RS4 disruption and increased anxiety. Applicant argues that the impaired coordination phenotype relates to motor function and coordination problems and that seizure disorders are clearly a disease or disorder (page 5, paragraph 2). Applicant also argues that it is generally viewed in the art that when a gene is knocked out in mice, that the resulting phenotype is representative of the function of that gene and that in the present case, the increased anxiety, decreased coordination and decreased susceptibility to seizure indicates a role for FPR-RS4 in these conditions (page 5, paragraph 3).

In response, the claimed phenotypes appear to be generic rather than specific to any disease. The specification fails to teach a role or function for FPR-RS4 that correlates to any disease or disorder related to any of the claimed phenotypes. Furthermore, the art of record fails to correlate the phenotype of decreased susceptibility to seizure to any disease. As set forth in the previous office action (refer to page 5), the art at the time of filing held that a single gene disruption cannot not be clearly correlated to the disease state of anxiety (refer to Belzung, 2001, Behavioral Brain Research, Vol. 125, pages 141-149) and therefore, the disruption of the FPR-RS4 gene does not clearly correlate to a disease state. With respect to the phenotype of decreased susceptibility to seizure, it is not clear how one would use a mouse exhibiting such a phenotype because mouse models of seizure disorder exhibit increased susceptibility to seizure

Art Unit: 1632

for the purpose of studying seizures and screening agents for the ability to ameliorate seizures. With respect to the phenotypes of decreased coordination and the newly added phenotype of impaired balance, the specification fails to provide teachings that would correlate these generic phenotypes to the claimed disruption or to a disease state. Without such teachings, it cannot be determined what one would use a mouse exhibiting impaired balance for and the asserted utility of screening for agents does not appear specific and substantial (refer to page 4 of the previous office action mailed 09/10/2003, page 4, 1st paragraph).

Claims 6,8,9,23,29-32 and 35-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following issue of enablement must also be addressed:

Claim 23 continues to encompass chimeric mice as step (a) is drawn to administering an agent to a transgenic mouse comprising a homozygous disruption in the FPR-RS4 gene (refer to pages 6-7 of the previous office action mailed 09/10/2003).

Applicant argues that the claims now relate to a transgenic mouse whose genome comprises a homozygous disruption in the FPR-RS4 gene. This argument is persuasive with the exception of claim 23, which was not amended with respect to this rejection. Therefore, the rejection is maintained as it relates to claim 23.

The rejection of claim 30 for being drawn to mice exhibiting ataxia is maintained (refer to page 7, paragraph 3 of the previous office action, mailed 09/10/2003). Claim 30 continues to encompass mice exhibiting ataxia using the mouse of claim 6, which does not exhibit ataxia.

Art Unit: 1632

Applicant argues that the rejection has been overcome by amending the claim to delete the term “ataxia” in the determining step. This argument is not persuasive as the preamble of the claim continues to recite “A method of identifying an agent that ameliorates...ataxia”, using the mouse of claim 6, which does not exhibit ataxia.

The rejection of claim 37 under 35 USC 112, 1st paragraph, New Matter, has been withdrawn in light of the amendment to the claim.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 6,8,9,29-32 and 35-39 under 35 USC 112, 2nd paragraph is withdrawn in light of the amendments to the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632


DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1632